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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/661,378	09/12/2003	Adrienne E. Dubin	ORT1502-CON	6696
7590 01/30/2006			EXAMINER	
Audley A. Ciamporzero, Jr. One Johnson & Johnson Plaza New Brunswick, NJ 08933-7003			BALLARD, KIMBERLY A	
			ART UNIT	PAPER NUMBER

1649

DATE MAILED: 01/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/661,378	<b>Applicant(s)</b> DUBIN ET AL.	
	<b>Examiner</b> Kimberly A. Ballard	<b>Art Unit</b> 1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 21 January 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-21 are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-9 and 14 each in part, drawn to a DNA molecule that encodes human 5-HT3-C protein, having the nucleotide sequence of SEQ ID NO: 4, expression vectors, recombinant host cells, and method of producing the protein comprising same, classified for example in class 536, subclass 23.1.
- II. Claims 1-9 and 14 each in part, drawn to a DNA molecule that encodes human 5-HT3-C protein, having the nucleotide sequence of SEQ ID NO: 5, expression vectors, recombinant host cells, and method of producing the protein comprising same, classified for example in class 536, subclass 23.1.
- III. Claims 10 and 11, drawn to a protein having the amino acid sequence of SEQ ID NO: 9, classified for example in class 530, subclass 350.
- IV. Claims 12 and 13, drawn to an antibody immunologically reactive with human 5-HT3-C protein, classified for example in class 424, subclass 130.1.
- V. Claim 15, drawn to a method of identifying compounds that modulate human 5-HT3-C protein activity, classified for example in class 435, subclass 7.1.

- VI. Claims 16-20 each in part, drawn to a compound that inhibits binding of, inhibits function of, or is an antagonist of the human serotonin 5-HT3 receptor complex, or modulates expression or activity of a 5-HT3-C subunit, classified for example in class 514, subclass 2.
- VII. Claims 16-20 each in part, drawn to a compound that enhances binding of, stimulates function of, or is an agonist of the human serotonin 5-HT3 receptor complex, or modulates expression or activity of a 5-HT3-C subunit, classified for example in class 514, subclass 2.
- VIII. Claim 21, drawn to a method of treating a patient for a condition that is mediated by a human 5-HT3-C, comprising administering a human 5-HT3-C modulating compound, classified for example in class 514, subclass 1.

The inventions are distinct, each from the other because of the following reasons:

Inventions I-IV and VI-VII are directed to related products. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, Inventions I-IV and VI-VII are directed to products that are distinct, each from the other, because they are products which possess characteristic differences in structure and function and each has an independent utility, that is distinct for each invention and which cannot be exchanged. The nucleic acids of Inventions I-II are each structurally and functionally distinct from each other. Further, the nucleic acids of Inventions I-II,

protein of Invention III, antibody of Invention IV, and compounds of Inventions VI-VII are not recited or required by each other. Further, the compounds of Inventions VI-VII are each functionally distinct as they recite opposing actions, and therefore are not required for use by each other.

Inventions V and VIII are directed to related processes. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, Inventions V and VIII are directed to methods that are distinct from each other in reagents, steps, and outcomes or functions, and are not required one for the other. For example, the method of Invention V recites identification of compounds that modulate 5-HT3-C protein activity whereas the method of Invention VIII recites treatment of a patient.

Inventions (I-IV, VI and VII) and (V and VIII) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Inventions (I-IV, VI and VII) and (V and VIII) are unrelated products and processes, wherein each is not required, one for another. For example, the claimed methods of Inventions V and VIII do not recite the use or production of the products of Inventions I-IV, VI, and VII.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and the search required for any one group is not required for any other group, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

***Advisory Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kimberly A. Ballard whose telephone number is 571-272-4479. The examiner can normally be reached on M-F 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Kimberly Ballard, PhD  
Art Unit 1649  
January 20, 2006

  
JANET L. ANDRES  
SUPERVISORY PATENT EXAMINER